UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/678,357	10/04/2000	Sven Mardh	SMAR.P001	4507

21121 7590 08/05/2004

OPPEDAHL AND LARSON LLP
P O BOX 5068
DILLON, CO 80435-5068

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/678,357	MARDH ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,15,18-30,32 and 39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,15,18-30,32 and 39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 5/24/2004 has been entered.

2. Claims 1-13, 16, 17, 31, and 33-38 have been canceled. Claims 14 and 18-23 have been amended.

3. Claims 14, 15, 18-30, 32, and 39-43 are under consideration.

Compliance with the Amendment Rules

4. Claims 39-43 of the amendment submitted 5/24/2004 does not comply with the amendment rules. The status of these claims are not identified by a parenthetical expression (previously presented). A new list of the claims including the mentioned correction is required.

Objections Withdrawn

5. Objection to drawings made in paragraph 5 of the office action mailed March 23, 2001 has been withdrawn in view of corrected drawings submitted by the applicants.

Rejections Moot

6. Rejection of claims 33- 38 made under 35 U.S.C. 102 (b) as being anticipated by Lindgren et al. is moot in view of cancellation of said claims.

7. Rejection of claims 16, 17, 31 and 33- 38 made under 35 U.S.C. 103 (a) as being obvious over Oksanen et al. in view of Ma et al. is moot in view of cancellation of said claims.

Rejection(s) Withdrawn

8. Rejection of claims 14, 15, 24-30 and 32 made under 35 U.S.C. 102 (b) as being anticipated by Lindgren et al. is withdrawn in view of applicants' amendments.

Rejection(s) Maintained

9. Rejection of claims 39-43 made under 35 U.S.C. 103 (a) as being obvious over Lindgren et al. is maintained.

The rejection is as stated below:

Claims 39-43 are rejected under U.S.C. 103 (a) as being unpatentable over Lindgren et al.

Claims 39-43 are drawn to a kit comprising reagents suitable for detecting H, K-ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Lindgren et al. teach a screening method for gastritis, evaluting blood samples for the presence of antibodies for H, K-ATPase , Helicobacter pylori and the concentration of pepsinogen A (pepsinogen I) . They also disclose that the antibodies to H, K-ATPase were determined using an enzyme- linked immunoabsorbent assay, *Helicobacter pylori* antibodies were determined using enzyme immunoassy, and pepsinogen I serum level was determined by a double -antibody radioimmunoassy. Lingren et al. did not teach a kit comprising the above reagents.

At the time the invention was made, it would have been prima facie obvious to a person of ordinary skill in the art to combine the reagents taught by Lindgren et al. in a single kit to expedite assay efficacy.

Applicants' arguments filed 05/24/2004 have been fully considered and are not persuasive.

Applicants argue, " These kits contain the reagents for the performance of multiple tests associated with the method of the invention. These tests are as far as Lindgren is concerned duplicative at best, and indeed one test is shown to be better than the others. ".

It is the examiner's position that Lindgren et al. teach the reagents as claimed by the applicants. At the time the invention was made, it would have been *prima facie* obvious to a person of ordinary skill in the art to combine the reagents and methods taught by Lindgren et al. in form of a kit for screening gastritis and one of ordinary skill in the art would have been motivated to assemble the reagents of well-known and obvious tests in form of a kit for mere convenience to simplify and optimize diagnostic techniques to detect multiple antibodies in the same sample. Supplying three immunoassay indicators in form of a kit comprising reagents suitable for the above well-known indicators, and including an immobilized solid support, labeled antibodies, and buffers are well known in the art. Assembling the reagents of well-known and obvious tests in form of a kit is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure. Claims 39-43 have not been amended by the applicants, therefore the rejection stands for the reason of record.

10. Rejection of claims 14, 15, 18, 30 32 and 39-43 made under 35 U.S.C. 103 (a) as being obvious over Oksanen et al. in view of Ma et al. is maintained.

The rejection is a stated below:

Claims are drawn to a method and a kit for screening gastritis assaying blood samples for the presence of H, K- ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Oksanen et al. evaluated serum samples to predict normal gastric mucosa by studying the serum samples for *Helicobacter pylori* antibodies by enzyme immunoassay (Pyloriset EIA-G and EIA-A) and pepsinogen I was measured by an immunoenzymometric assay (Gastrotest PGI). Oksanen et al. did not teach assaying for H, K-ATPase antibodies.

Ma J.Y. et al. studied sera from patients with pernicious anemia by means of enzyme-linked immunosorbent assay for the occurrence of antibodies against H, K-ATPase and *Helicobacter pylori.* Ma J.Y. et al. do not teach Elisa to measure pepsinogen I levels.

Limitations such as higher or lower level of the indicators or calculating ratios of the indicators are being viewed as limitations of optimizing experimental parameters.

At the time the invention was made, it would have been prima *facie* obvious to a person of ordinary skill in the art to combine the two antibody assay methods and kits taught by Oksenen et al with the method taught by Ma J.Y. et al in form a kit for screening gastritis. The analysis of multiple analytes or more indicators associated with gastritis provides reliable method for diagnosing gastritis.

One of ordinary skill in art would have been motivated to do this in order to obtain a method and a kit to simplify and optimize diagnostic techniques to detect multiple antibodies in the same sample.

Applicants' arguments filed 05/24/2004 have been fully considered and are not persuasive.

Applicants argue, that the references teach separate assays for gastritis and the examiner argues that the combination of the assays would have been obvious. Applicants further argue that the burden is on the examiner to establish a reason to do the assays from the separate references and to show that there is an expectation from this art that the test results should be viewed in combination to arrive at diagnosis and type of gastritis.

It is the examiner's position that the applicants appear to argue that the references individually without clearly addressing the combination of references. It must be remembered that the references are relied upon in combination and are not meant to be considered separately in a vacuum. It is the combination of all the cited and relied upon references, which make up the state of the art with regard to the claimed invention. Applicants claimed invention fails to patentably distinguish over the state of art represented by the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In *re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

It is well known in the art of medicine and clinical diagnosis to evaluate multiple tests done separately in combination to arrive at diagnosis and type of a disease i.e. gastritis.

Limitations such as higher or lower level of the indicators or calculating ratios of the indicators are still being viewed as limitations of optimizing experimental parameters.

11. Rejection of claims 39-43 made under 35 U.S.C. 103 (a) as being as being

unpatentable over Lindgren et al. in view of Harkonen, M. (WO 96/15456) is maintained. The rejection is as stated below:

Claims 39-43 are drawn to a kit comprising reagents suitable for detecting H, K-ATPase antibodies, *Helicobacter pylori* antibodies, and Pepsinogen I.

Lindgren et al. teach a screening method utilizing reagents for evaluating blood samples for the presence of antibodies for H, K-ATPase, *Helicobacter pylori* and the concentration of pepsinogen A (pepsinogen I). Lindgren et al. did not teach a kit. However, Harkonen teaches a kit for determination of serum pepsinogen I, *Helicobacter pylori* antibodies and gastrin (see claim 12 and page 10).

It would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the invention was made to combine the reagents and methods taught by Lindgren et al. and Harkonen and replace the gastrin antibody with antibodies to H, K-ATPase in the kit to obtain the instant invention. One of ordinary skill in art would have been motivated to do this in order to make a kit to simplify and optimize diagnostic techniques to detect multiple indicators in the same sample.

Applicants' arguments filed 05/24/2004 have been fully considered and are not persuasive. Applicants argue, this rejection seems largely based on the erroneous interpretation of Lindgren as a teaching that uses all of the claimed reagents in an integrated test.

It is the examiner's position that Lindgren et al. teach the reagents as claimed by the applicants and assembling the reagents of well-known and obvious tests in form of a kit

is for mere convenience and does not impart any criticality on the patentability of a well-known test or procedure.

Claims 39-43 have not been amended by the applicants, therefore the rejection stands for the reason of record.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645, August 1, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER